REMARKS

With this amendment, Claims 1-8 and 10-12 are pending in the application.

1. (a through i) Claims 5, 6, 10 and 13 have been rejected by the Office as being vague and indefinite under 35 USC 112, second paragraph. With respect to the Examiner's remarks at a. A-E, it is respectfully suggested that the present application adequately teaches how to make Applicants' compound, how to use it to obtain an appropriate and/or usable form of the claimed compound in the claimed formulation to treat a mammal by applying routine skills in the pharmaceutical arts. Claims 5 and 6 now state the step of administration "to a mammal", basis for which is found in the specification at page 4, lines 6-10. Claim 10 has had its formula corrected and the placement of "periods" modified per USPTO rules. Claim 13 has been cancelled. In view of these amendments to Claims 5, 6, 10, and 13, this rejection of the claims is rendered moot.

2. The Examiner has rejected Claims 1-8 and 13 under 35 USC 102 as anticipated by or in the alternative under 35 USC 103(a) as obvious over Hirst et al. Journal of Medicinal Chemistry. It is the Examiner's position that Example 29 (aka GW 7854), in Table 2 of Hirst (page 5240, Column 2, second full paragraph) discloses a potent mixed CCK-A agonist/CCK-B antagonist.

It is Applicants' contention that the Hirst reference does not anticipate nor render obvious the claimed enantiomer of Applicants' invention. Example 29 is a racemate. There is no teaching nor suggestion in Hirst to employ an enantiomer, muchless Applicants' claimed enantiomer. Accordingly, it is respectfully requested that the Examiner reconsider and withdrawn this rejection of the claims.

3. The Examiner has rejected Claims 1-8 and 13 under 35 USC 102 as anticipated by or in the alternative under 35 USC 103(a) as obvious over U.S. Patent No. 5,646,140 to Sugg *et al.* It is the Examiner's position the '140 patent teaches the compounds, the compositions, and method of use of Applicants' claimed compound. According to the Examiner, Example 7,

teaches the compound of the present invention and enatiomers are included at column 5, lines 30-46.

It is Applicants' contention that the '140 patent does not anticipate nor render obvious the claimed enriched enantiomer compound of Applicants' invention. The '140 patent discloses a large class of 3-amino-1,5-benzodiazepines as exhibiting CCK-A receptor and notes that certain of these compounds have antagonist activity at CCK-B receptors (Column 1, lines 60-65). The '140 patent discloses salts, solvates, stereoisomers including isomers of optically active racemic compounds of this class of 3-amino-1,5-benzodiazepines (Column 5, lines 30-67). Also, at Column 5, lines 3-17, particularly preferred compounds of the '140 patent are recited. Example 7, pointed out by the Examiner does not belong to this preferred group of compounds. Further, Example 7 is a racemate not Applicants' claimed enantiomer. There is nothing in the '140 patent to motivate one of ordinary skill in the art to modify Example 7 to Applicants' enriched +-enantiomer compound. There is no motivation for wanting to make Applicants' enantiomeric compound in preference to all the others compounds in the '140 patent. Without motivation, the ability to make a compound is beside the point. It is only the impermissible use of hindsight gained from Applicants' patent application that has led the Examiner to use the '140 patent in this manner. Accordingly, this rejection is improper. It is respectfully requested that this rejection of the claims be reconsidered and withdrawn.

4. The Examiner has rejected Claims 1-8 and 13 of the present application under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8, and 17 of the '140 patent. It is the Examiner's position that although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions, and method of use of the compound of the instant invention are embraced by the compounds, compositions, and method of use claimed in the '140 patent.

While the claims of the '140 patent broadly encompass an enantiomer of the racemic compound of Example 7 of the patent, the enantiomerically enriched compound of the present invention is not obvious in view of the

claims of the '140 patent. The unexpected biological activities that distinguish the enriched (+)-enantiomer of the present invention from its (-)-enantiomer and the racemate (such as the one in Example 7 of the '140 patent) are set forth in the present application at pages 26-27. In view of the non-obvious aspects of the present invention set forth in the application at pages 26-27 and lack of motivation for one of ordinary skill in the art to make applicant's claimed enantiomer, it is respectfully requested that this rejection of the claims be reconsidered and withdrawn.

5. The Examiner has rejected Claims 4 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6, and 10 of U.S. Patent No. 5,780,464. It is the Examiner's position that, although the pharmaceutical compositions of Claims 4 and 13 of the present invention are not identical to those in '464 patent, they are not patentably distinct from each other because the compositions of the instant application are embraced by those in the '464 patent.

While the claims of the '464 patent broadly encompass a pharmaceutical formulation employing an enantiomer, the enantiomerically enriched compound of the present invention is not obvious in view of the claims of the '464 patent. The unexpected biological activities that distinguish a pharmaceutical formulation of the enriched (+)-enantiomer of the present invention from its (-)-enantiomer and its racemate are set forth in the present application at pages 26-27. In view of the non-obvious aspects of the present invention set forth in the application at pages 26-27 and lack of motivation for one of ordinary skill in the art to make applicant's claimed enantiomer, it is respectfully requested that this rejection of the claims be reconsidered and withdrawn.

6. The Examiner has rejected Claims 5-8 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 5,910,495. It is the Examiner's position that although Claims 5-8 and 13 of the present application are not identical, they are not patentably distinct from those in the '495 patent because the

method of use claims of the present invention are embraced by the method of use claims of the '495 patent.

While the claims of the '495 patent broadly encompass a method of use employing an enantiomer, the method of use of Applicants' particular enantiomerically enriched compound of the present invention is not obvious in view of the claims of the '495 patent. The unexpected biological activities that distinguish the enriched (+)-enantiomer of the present invention from its (-)-enantiomer and its racemate are set forth in the present application at pages 26-27. In view of the non-obvious aspects of the present invention set forth in the application at pages 26-27 and lack of motivation for one of ordinary skill in the art to make applicant's claimed enantiomer, it is respectfully requested that this rejection of the claims be reconsidered and withdrawn.

7. Claims 11 and 12 have been objected to under 37 CFR 1.75c as being in improper form because a multiple dependent claim must be in the alternative. This has been corrected making this objection moot.

In view of the foregoing amendments and arguments, it is respectfully requested that the present application be reconsidered and allowed.

Respectfully submitted,

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